UNITED STATES PATENT AND TRADEMARK OFFICE

10/001,8[illegible]	11/20/2001	Susana Salceda	[illegible]	[illegible]

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Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,876	SALCEDA ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7-9, and 15 (in part), drawn to an isolated nucleic acid, host cell, vector, a kit comprising a nucleic acid and method of producing a polypeptide, classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1 and 325, for example.

II. Claims 6 and 14 (in part), drawn to a method for determining the presence of a prostate specific nucleic acid, classified in class 435, subclass 6, for example.

III. Claims 10-11 and 15 (in part), drawn to polypeptides and a kit comprising polypeptides, classified in class 530, subclass 350, for example.

IV. Claim 12, drawn to an antibody, classified in class 530, subclass 387.1, for example.

V. Claim 13, drawn to drawn to a method for determining the presence of a prostate specific protein using an antibody, classified in class 435, subclass 7.1, for example.

VI. Claim 14 (in part), drawn to a method for diagnosing and monitoring the presence and metastases of prostate cancer by determining the amount of a polypeptide, classified in class 435, subclass 4, for example.

VII. Claim 16, drawn to a method of treating prostate cancer by administering an antibody, classified in class 514, subclass 2, for example.

VIII. Claim 17 (in part), drawn to a vaccine comprising a nucleic acid, classified in class 514, subclass 44, for example.

IX. Claim 17 (in part), drawn to drawn to a vaccine comprising a, classified in class 514, subclass 21, for example.

2. In addition to electing one Group detailed above, Applicants are also required to elect a **single** nucleic acid, polypeptide or antibody (dependant on which group above is elected). If a method is elected, Applicants must elect a **single** nucleic acid, polypeptide or antibody that is used in the elected method (dependant on which group above is elected). Each nucleic acid, polypeptide and antibody is patentably distinct from one another, as each is structurally and functionally different.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, III, IV, VIII and IX are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I and the vaccine of Group VIII are composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The polypeptide of Group III and the vaccine of IX are composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group IV is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer.

Furthermore, the products of Groups I, III, IV, VIII and IX can be used in materially different processes. For example, the DNA of Group I can be used in a hybridization assay, the antibody of Group IV can be used in a immunoassay, the polypeptide of Group III can be used to make a fusion protein with an enzymatic function, and the vaccines of Group VIII and IX can be used in methods of preventing prostate cancer. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, III, IV, VIII and IX are patentably distinct from each other.

B) Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acid of Group I can be used in a materially different method, such as in an amplification method or a method of treating.

C) Inventions I and V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation, different functions, and different effects and are not disclosed as capable of use together because the nucleic acids of Group I are not required to practice the methods of Groups V-VII.

D) Inventions II and V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

the inventions are directed to methods having different method steps, starting materials, and goals.

E) Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the vaccine of Group VIII can be used in a materially different method, such as in a method of preventing prostate cancer.

F) Inventions II and III, IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products of Groups III, IV and IX have different functions and effects and are not used in the method of Group II.

G) Inventions III and (V and VII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptide of Group III has different function and effects, and is not used in the methods of Groups V and VII.

H) Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, the polypeptide of Group III can be used in a materially different method, such as in a method of preventing prostate cancer or in a purification assay.

I) Inventions IV and (V and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Group IV can be used in materially different methods, such as immunoassays, methods of determining the presence of a prostate specific protein or in methods of treating a patient.

J) Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Group IV has different function and effects, and is not used in the method of Group VI.

K) Inventions V-VII and (VIII and IX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the vaccines of Groups VIII and IX have different function and effects, and are not used in the methods of Group V-VII.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IX require different searches that are not co-

extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
April 7, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER